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April 15, 2024

The Honorable Jennifer L. Hall
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801-3555

VIA ELECTRONIC FILING

Re: *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*,
C.A. No. 21-1015 (JLH)

Dear Judge Hall:

In response to the Court's April 12, 2024 Oral Order (D.I. 525), the parties provide the following list of remaining claims and defenses, the motions that still need to be resolved, and the portions of motions that may be disregarded as moot.

The following claims and defenses remain in the case:

- Nippon Shinyaku Co., Ltd.'s (NS's) claims for patent infringement and damages, and Sarepta's obviousness defense.
 - NS's seven originally asserted patents are all from one patent family, and NS has agreed to narrow to no more than 6 total representative claims encompassing the remaining five asserted patents.
 - Sarepta has agreed to assert no more than three total references in its obviousness combinations (in addition to references used purely for background or to demonstrate a reasonable expectation of success).
- Sarepta's claims for patent infringement and damages, and NS's noninfringement, lack of enablement, lack of written description, and indefiniteness defenses (though Sarepta disputes that indefiniteness is properly in the case).
 - Sarepta's three originally asserted patents are all from one patent family, and Sarepta has agreed to narrow to no more than two total representative claims

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selected from claims 1-2 of U.S. Patent No. 9,994,851; claims 1-2 of U.S. Patent No. 10,227,590; and 1-2 of U.S. Patent No. 10,266,827.

- Both sides' unenforceability defenses.
- NS's breach of contract claim.
- NS's and NS Pharma, Inc.'s (NS Pharma's) *Walker Process* antitrust claims.

The parties agree that certain issues in this case are issues for the Court to determine—namely, each side's inequitable conduct claim. NS and NS Pharma request that the Court submit the question of whether the parties' asserted patents are unenforceable for inequitable conduct to the jury for an advisory verdict. Sarepta submits that inequitable conduct should be decided by the Court at a later time.

The parties also agree that NS's breach of contract claim be decided by the Court.

NS and NS Pharma contend that the *Walker Process* antitrust claim which is based on the assertion of unenforceable patents should be tried to the jury as part of the upcoming trial. Sarepta's position is that NS's and NS Pharma's *Walker Process* antitrust claim should be bifurcated from the patent issues and tried to a separate jury if it is not mooted by decisions in the May 13 trial, the Court's resolution of the inequitable conduct defenses at a to-be-scheduled bench trial, or is otherwise resolved. The parties' positions regarding Sarepta's proposed bifurcation are set forth in the briefing regarding Sarepta's Motion to Bifurcate and Stay Antitrust Counterclaim. Under Sarepta's proposal, the following motions in the list below can be postponed until after the May 13 trial: 4a(iii); 4a(vi); 4(vii); 5a(i); 5(a)(iv); and 5a(v).

Motions That Need Resolution or Are Moot

1. Antitrust Motions:

a. Needs resolution:

- i. Sarepta's and the University of Western Australia's Motion to Bifurcate and Stay Antitrust Counterclaim (D.I. 351, 356, 356-1, 356-2, 358, 358-1)

b. Moot:

- i. Sarepta's and the University of Western Australia's Motion to Stay Antitrust Counterclaim Deadlines Pending Resolution of Sarepta's and the University of Western Australia's Motion to Bifurcate and Stay (D.I. 353, 360, 363)

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2. Motions related to NS's technical expert, Dr. Matthew Wood:

a. Needs resolution:

- i. Sarepta's Motion to Exclude Dr. Matthew Wood as an Expert Witness (D.I. 220, 298, 299, 308, 309, 313)
- ii. Sarepta's Motion for Leave to File a Reply in Support of Its Motion to Exclude Dr. Wood as an Expert Witness (D.I. 321)
- iii. Sarepta's Motion to Strike Dr. Matthew Wood's Expert Reports (D.I. 384, 385, 385-1, 389, 389-1)

b. Moot:

- i. Nippon Shinyaku's Motion Regarding Disclosure of Sarepta-Designated Information to Dr. Matthew Wood (D.I. 220, 300, 300-1, 307, 307-1)
- ii. Nippon Shinyaku's Motion for Leave to File Reply Letter Brief Regarding Disclosure of Sarepta-Designated Information to Dr. Matthew Wood (D.I. 320)

3. Discovery Disputes:

a. Moot:

- i. Nippon Shinyaku's and NS Pharma's Objections to Special Master Order No. 1 Denying Motion to Compel Production of License Agreements (D.I. 285, 286, 304, 305)
- ii. Nippon Shinyaku's Motion for Leave to Serve Amended Final Infringement Contentions (D.I. 301, 301-1)

4. Motions for Summary Judgment:

a. Needs resolution:

- i. Sarepta's Motion for Summary Judgment of Infringement of U.S. Patent Nos. 9,994,851 and 10,227,590 (D.I. 396, 409, 411, 460, 461, 490, 491)
- ii. Sarepta's Motion for Summary Judgment of No Lost Profits (D.I. 397, 409, 411, 462, 463, 490, 491)
- iii. Sarepta's Motion for Summary Judgment of No Inequitable Conduct and No *Walker Process* Fraud (D.I. 398, 409, 411, 464, 465, 466, 490, 491)
- iv. NS's and NS Pharma's Motion for Summary Judgment No. 1 – Invalidity of the UWA Patents (D.I. 399, 400, 401, 469, 470, 471, 472, 493, 495, 496, 496-1, 496-2)
- v. NS's and NS Pharma's Motion for Summary Judgment No. 2 – Infringement of Certain NS Patents (D.I. 402, 403, 404, 469 (p. 24), 470 (p. 12), 471, 472, 473, 493, 495, 496, 496-1, 496-2)

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- vi. NS's Motion for Summary Judgment No. 3 – Breach of Contract (D.I. 405, 406, 407, 469 (pp. 24-28), 470 (pp. 13-16), 471, 472, 493, 495, 496, 496-1, 496-2)
 - vii. NS's Motion for Partial Summary Judgment No. 5 – No Inequitable Conduct (D.I. 414, 415, 416, 469, 470, 471, 472, 493, 495, 496, 496-1, 496-2)
 - b. Moot:
 - i. NS's Motion for Summary Judgment No. 4 – No Anticipation (D.I. 408, 410, 412, 469 (pp. 28-32), 470 (pp. 17-19), 471, 472, 493, 495, 496, 496-1, 496-2)
5. *Daubert* Motions:
- a. Needs resolution:
 - i. Sarepta's Motion on Exclusion of Dr. Kamholz's Opinions and Testimony Regarding Inequitable Conduct (D.I. 391, 395, 456, 489)
 - ii. Sarepta's Motion on Exclusion of Dr. Esau's Non-Infringement Opinion and Testimony (D.I. 392, 395, 457, 489)
 - iii. Sarepta's Motion on Exclusion of the "State of Mind" Opinions and Testimony of NS's Experts (D.I. 393, 395, 458, 489)
 - iv. NS's and NS Pharma's Motion to Exclude the Testimony and Opinions of Sarepta's Technical Expert Steven F. Dowdy, Ph.D. (D.I. 419, 421, 467, 471, 472, 494, 496, 496-1, 496-2)
 - v. NS and NS Pharma's Motion to Exclude the Testimony and Opinions of Sarepta's Expert Andrew Hirshfeld Related to Legal Opinions (D.I. 423, 424, 467, 471, 472, 494, 496, 496-1, 496-2)
 - b. Moot:
 - i. Sarepta's Motion on Exclusion of Dr. Luedtke's Doctrine of Equivalents Opinions and Testimony (D.I. 394, 395 (pp. 14-20), 459, 489 (pp. 7-8))

The parties are available to discuss the above issues at the Court's convenience.

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Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via electronic mail)